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2000 '00 AUG 14 A9:48

August 11, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 00D-1305 Draft Compliance Policy Guide - Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin

Dear Sir or Madam:

The National Juice Products Association ("NJPA") submits the following comments on the docket item referenced above. NJPA member companies produce a wide range of fruit juices and juice beverages, including apple juices and apple juice products. Our members process fruit into juice, buy and sell bulk and packaged fruit juices throughout the world, and many U.S.-based NJPA members import fruit juices into the United States from other production areas. For this reason, the docket item involving patulin in apple juice products is of great interest to NJPA. Attached as Appendix A is a list of NJPA's current membership.

As FDA is aware, controlling patulin in apple juice is complicated and involves numerous factors in apple juice manufacturing – from the process of harvesting apples to the packaging of apple juice for the consumer. Patulin contamination is considered within the juice industry to be a manufacturing defect. Because there are potential safety implications to this defect, NJPA supports FDA's involvement in seeking reasonable limits and controls.

NJPA supports the proposed guidance on agency adulteration determinations where a product contains patulin at or above 50 parts per billion (as determined on a single strength basis). This action level has wide industry acceptance. The limit is also reasonable given the safety assessment and the constraints inherent in dealing with natural food products such as apples. The 50 p.p.b. level has been recommended by NJPA in the past as an appropriate level, and is included in the draft Codex Standard for Fruit Juices and Nectars, currently at Step 3 and to be discussed by the Ad Hoc Codex Intergovernmental Task Force on Fruit and Vegetable Juices in September 2000.

A formal action level for patulin in the United States will remove some of the

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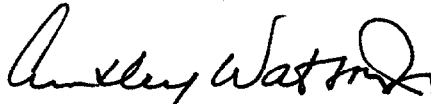
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doubt that currently exists in the apple juice trade. In the absence of a formal action level, manufacturers have little basis for excluding certain receipts of apple juice. NJPA believes the proposed action level will promote fair dealing within the trade, as well as consumer safety.

We hope these comments have been helpful. If NJPA can be of any assistance on this issue, please feel free to contact us.

Sincerely,

A handwritten signature in dark ink, appearing to read "Ansley Watson, Jr.", with a stylized flourish at the end.

Ansley Watson, Jr.
Executive Director

AWjr/kcg/a
Enclosure

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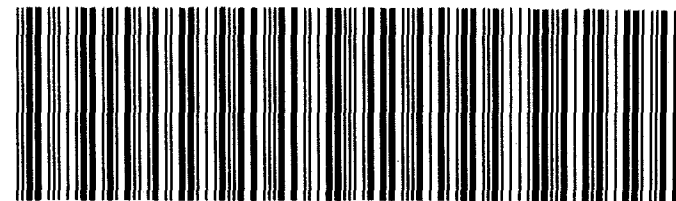
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